**EXECUTIVE SUMMARY** 

# **Transforming Research**

To Prevent, Detect, Treat, and Provide Better Care for Dementia



Each year since 2015, the National Institutes of Health (NIH) has presented a professional judgment budget (sometimes referred to as a "bypass budget") for additional federal funds needed for research to effectively treat or prevent Alzheimer's disease and related dementias by 2025. These bypass budget reports feature highlights of recent science advances toward that goal.

For full details, visit www.nia.nih.gov/bypass-budget.

#### **Funding to Support Relevant Research**

For fiscal year (FY) 2023, additional NIH resources needed for new Alzheimer's and related dementias research are **\$226 million**, which would bring the total FY 2023 NIH resource needs for these areas of research to **\$3.4 billion**. NIH's Alzheimer's and related dementias funding supports a broad area of relevant research across multiple Institutes and Centers.

#### Millions of Americans Live With Dementia

It is estimated that as many as 6.25 million Americans now have <u>Alzheimer's disease</u>, and the prevalence in the United States is projected to more than double to 13.85 million by 2060. Although Alzheimer's is the most common dementia diagnosis, many people have cognitive impairment from other conditions such as <u>Lewy body dementia</u>, frontotemporal dementia, and vascular dementia.



#### **Dementia Health Disparities**

Like many other conditions, Alzheimer's disease continues to have a disproportionate impact across racial and ethnic groups. Between now and 2060, the number of Black/African Americans with Alzheimer's is expected to increase from about 1.1 million to 3.1 million. The number of Hispanic/Latino Americans living with the disease is expected to increase from about 0.76 million to 3.7 million. These facts and projections underscore the critical need for research participants to better reflect the diversity of the U.S. population.

	Black	Latino	Non-Hispanic White	Total
2021	1.1 million	.76 million	4.4 million	6.25 million
2060	3.1 million	3.7 million	7.0 million	13.85 million

#### More than

## **260,000** <u>deaths</u> per year

Deaths from these diseases are a leading cause of mortality in the U.S.: More than 260,000 Americans die each year from Alzheimer's and related dementias combined.

## FDA Approves First New Alzheimer's Drug Since 2003

In June 2021, the Food and Drug Administration (FDA) granted accelerated approval of aducanumab for the treatment of Alzheimer's. While the NIH provided no direct support for the drug development of aducanumab, years of public funding were integral. For example, NIH's National Institute on Aging (NIA) supported basic science investigations behind the discovery of immunotherapies similar to aducanumab, as well as translational research for nextgeneration immunotherapies. Additionally, the selection of participants for aducanumab clinical trials hinged on positron emission tomography (PET) scans for amyloid plaques. Amyloid PET imaging is a method that would not exist today without

#### Previous Investments Bolstered COVID-19 Research

the NIH-supported research.

NIA helped address challenges experienced by people living with dementia and their care partners during the COVID-19 pandemic. For example, the NIA-funded IMbedded Pragmatic Alzheimer's Disease and AD-Related Dementias Clinical Trials (IMPACT) Collaboratory, a previously established network of partnering health care systems, was primed and ready to pivot quickly and effectively to respond to the pandemic with new research. IMPACT researchers found that cognitive impairment is linked to higher death rates in nursing home residents with COVID-19. Additionally, they received NIA funding supplements to better understand several aspects of COVID-19 and its effect on people living with dementia, including how to improve testing for COVID-19 in skilled nursing facilities, and to evaluate infection control in nursing homes in Massachusetts.

#### Scientific Progress

The FY 2023 bypass budget report summarizes NIHsupported Alzheimer's and related dementias research achievements in the following areas:

## Developing effective, less invasive diagnostic and detection methods through biomarker research

NIH continues to invest in the development of easier-to-use, less cost-restrictive tests for early detection and diagnosis for Alzheimer's and related dementias. In 2020 — thanks in part to NIH funding — the first blood test for amyloid, a biomarker for Alzheimer's, became available to doctors. Also in 2020,

FDA approved the first diagnostic agent for detecting tau tangles in brain scans. NIA-funded research demonstrated the safety and effectiveness of this diagnostic.

#### Enhancing diversity and reducing health disparities

NIH efforts include providing undergraduate students from underrepresented backgrounds with opportunities to explore research careers, and developing and implementing initiatives to increase diversity in clinical trial participants. Additionally, NIA created new funding opportunities to explore why there are detrimental differences in dementia cases and care among diverse populations.

## Looking for new drug candidates and working to repurpose FDA-approved drugs for dementia

A range of treatments and precision medicine approaches are needed to successfully halt or reverse the effects of Alzheimer's and related dementias. NIA is funding several new projects focused on developing new drugs, or repurposing drugs already approved for other health conditions, that target a wide range of the biological processes that lead to these diseases.

## Funding studies of healthy behaviors that may reduce the risk of dementia

NIA-funded researchers are also exploring lifestyle and behavioral interventions — such as cognitive training, healthy eating, and exercise, as well as combinations of these strategies — as ways to prevent or slow the progression from mild cognitive decline to dementia. For example, a recent NIA-funded analysis indicated that people who get enough physical activity, keep the mind active, avoid smoking, and choose a high-quality diet are at substantially lower risk for Alzheimer's.

#### Improving the quality of care, life, and caregiving

The 2020 National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers brought together researchers, people living with dementia, care partners, providers, and advocates. Goals included evaluating evidence-based programs, strategies, approaches, and other research to improve the quality of care and of life for those living with dementia and their caregivers. The summit also provided a platform for identifying gaps and opportunities in research.

### Investing in centralized data-sharing platforms to transform collaborative research

NIH continues to invest in technologies that make it possible for scientists to share data, tissue samples, methods, and other crucial research resources more broadly and effectively. For example, through the Accelerating Medicines Partnership programs and the Alzheimer's Disease Sequencing Project, researchers are transforming how data and biological samples are shared openly, biological targets are discovered, and drug candidates are selected and developed.

